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TRANSMITTAL LETTER Docket No. (General - Patent Pending) **Army 160** In Re Application Of: Sherman Filing Date Examiner Customer No. Group Art Unit Confirmation No. Application No. 4/6/00 30951 1648 7634 09/544,108 Boesen, A. Title: Composition and Method of Treating Hepatitis C **COMMISSIONER FOR PATENTS:** Transmitted herewith is: Reply Brief postcard receipt in the above identified application. No additional fee is required. A check in the amount of is attached. The Director is hereby authorized to charge and credit Deposit Account No. 21-0380 as described below. Charge the amount of \boxtimes Credit any overpayment. Charge any additional fee required. ☐ Payment by credit card. Form PTO-2038 is attached. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. Dated: January 2, 2009 Caroline Nash, Reg. No. 36,329 (540) 554-4551 I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on January 2, 2009

CC:

Signature of Person Mailing Correspondence

Caroline Nash
Typed or Printed Name of Person Mailing Correspondence



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Government of the United States, As represented by the Secretary of the Army

Inventor(s) Kenneth Sherman, et al.

Technology Center: 1600

Appln. No.: 09/544,108

Group Art Unit: 1648

Filed: April 6, 2000

Examiner: Boesen; A.

Title: COMPOSITION AND METHOD OF TREATING HEPATITIS C

REPLY BRIEF

RESPONSE TO EXAMINER'S ANSWER

Hepatitis B and Hepatitis C are different diseases. A treatment for one virus would not be expected to be effective against the other virus. Hepatitis C is caused by an RNA virus and Hepatitis B is caused by a DNA virus (emphasis added). These two types of viruses operate differently in a host. For Hepatitis C, the injury is caused by the virus itself. For Hepatitis B, the injury is caused by the immunologic response to the virus.

The Examiner's assertion that a combination treatment for Hepatitis C is obvious and would be expected to be effective is not supported. Given that Hepatitis B injury is caused by the immunological response to the virus, an upsetting of the complex human immune response, thymosin's role in the treatment of Hepatitis B is complex. To state that thymosin would be expected to have the same role in treating Hepatitis C wherein the injury is caused by the virus itself rather than the immune response to the virus is totally unsupported.

There are other differences between the two diseases as well. About 30% of persons with Hepatitis B show no symptoms. About 80% of persons with Hepatitis C show no symptoms. Hepatitis C is less likely than the other hepatitis viruses to cause serious illness at first (only one-quarter of the people infected actually develop symptoms). There is a vaccine for preventing Hepatitis B that is available for all age groups that prevents hepatitis B virus infection (available sine 1982). There is no vaccine for preventing hepatitis C. No generalized assumption would have been made by one of ordinary skill in the art that a vaccine that works for one type of Hepatitis would work for the other type and further, no generalized assumption could have been made at the time of the invention that a therapy that works for Hepatitis B would also work for Hepatitis C.

Although Hepatitis B virus and Hepatitis C virus affect the liver, so do a host of other viruses such as the viruses that cause the mumps, measles, herpes and infectious mononucleosis. It is respectfully submitted that the Examiner's argument that because both Hep B and Hep C are viruses that affect the liver, a treatment for one would work for the other cannot be supported. One would also have to speculate that the same

Serial No.: 09/544,108

treatment would work for mumps, measles, herpes and mononucleosis using such logic because they are all viruses that cause Hepatitis. Applicants respectfully submit that one of ordinary skill in the art at the time of the invention would not have made that assumption.

Reconsideration and allowance of the claimed invention is respectfully requested.

Date:

Respectfully submitted,

Caroline M. Nash

Reg. No. 36,329

Customer No: 30951

Nash & Titus, LLC 21402 Unison Road Middleburg, VA 20117

(540) 554-4551

for: Elizabeth Arwine, Reg. No. 45,867

U.S. Army Medical Research and Materiel Command

Fort Detrick, MD 21702-9223